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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/762,210	01/20/2004	Ronald J. Berenson	IVGN 837.5 2519		
	7590 05/07/2007 CORPORATION	EXAMINER			
C/O INTELLE	· · · · · ·	KIM, TAEYOON			
P.O. BOX 5205 MINNEAPOLI	· <del>-</del>	ART UNIT	PAPER NUMBER		
			1651		
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		·	05/07/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Application No.	Application No. Applica		cant(s)			
		10/762,210	1	BERENSON ET AL.				
		Examiner		Art Unit				
		Taeyoon Kim		1651				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
WHIC - Exten after S - If NO - Failure Any re	DRTENED STATUTORY PERIOD FOR REPHEVER IS LONGER, FROM THE MAILING sions of time may be available under the provisions of 37 CFR (SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by statutely received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMN 1.136(a). In no event, however, d will apply and will expire SIX ( ute, cause the application to bed	MUNICATION. may a reply be timel  (6) MONTHS from the come ABANDONED	y filed e mailing date of this comi				
Status								
2a) <u>□</u> 3) <u>□</u>	Responsive to communication(s) filed on <u>24</u> This action is <b>FINAL</b> . 2b) The Since this application is in condition for allow closed in accordance with the practice under	is action is non-final. ance except for forma			nerits is			
Disposition	on of Claims							
5)□ 6)⊠ 7)□	Claim(s) 22 and 23 is/are pending in the app la) Of the above claim(s) is/are withdreclaim(s) is/are allowed.  Claim(s) 22 and 23 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and	awn from consideratio						
Application	on Papers							
ר <u> </u> [10	The specification is objected to by the Examir The drawing(s) filed on is/are: a) ac Applicant may not request that any objection to th Replacement drawing sheet(s) including the corre The oath or declaration is objected to by the B	ccepted or b) objector e drawing(s) be held in a ection is required if the dr	abeyance. See 3 awing(s) is objec	37 CFR 1.85(a). cted to. See 37 CFR				
Priority u	nder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
2) 🔲 Notice 3) 🔯 Inform	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date 3/26/07, 1/24/07.	Papı 5) 🔲 Noti	rview Summary (P er No(s)/Mail Date ce of Informal Pate er:	·				

### **DETAILED ACTION**

Claims 22 and 23 are pending.

It is noted that the current application has been reassigned to the current examiner.

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on Jan. 24, 2007 has been entered.

# Response to Amendment/Arguments

Applicant's amendment and response filed on Oct. 26, 2006 has been received and entered into the case.

Applicant argued that the cited reference does not anticipate the present invention because of the amendment made to the claims. However, this argument is not found persuasive because the amendment does not obviate the rejection. Applicant amended claims to have limitation of "simultaneous T cell concentration and cell surface moiety ligation". This limitation has been met by the method of Creson et al. because the method of Creson et al. utilizes a paramagnetic bead such as Dynabead M-450 which is used for simultaneous stimulation because of magnetic field applied to the beads coated with anti-CD3 and anti-CD28 antibodies to ligate and concentrate the

cells having CD3 and CD28 ligands. Therefore, the new limitation in the amended claims are anticipated by the reference. As discussed below, a step of applying magnetic force (field) is an inherent method step associated with the method of Creson et al. to stimulate T cells with magnetic beads coated with anti-CD3 and anti-CD28 antibodies.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Creson et al. (1999).

Claims 22 and 23 are drawn to a method for activating and expanding a population of regulatory T cells by simultaneous T cell concentration and cell surface moiety ligation, comprising contacting a population of cells comprising regulatory T cells with a paramagnetic particle where first and second agents are co-attached, applying a magnetic force to drive T cell concentration and T cell surface moiety ligation to induce activation and expansion of regulatory T cells (claim 22); a limitation to the method wherein the first agent being an anti-CD3 antibody or an antigen-binding fragment thereof, and the second agent being an anti-CD28 antibody or an antigen-binding fragment thereof (claim 23).

Creson et al. teach the activation and expansion of T cells using anti-CD3 and anti-CD28 antibodies attached to magnetic beads such as Dynabead M-450 (see p. 9338, Materials and Methods). Dynabead M-450 is a paramagnetic particle as disclosed in the specification of the current application (see p.30, lines 20-23). Although Creson et al. do not particularly disclose a step of applying a magnetic force to drive T cell concentration onto the beads via T cell surface moiety ligation, this step is inherently achieved by the method of Creson et al. using paramagnetic beads to stimulate T cells. Because the method steps of activating and expanding T cell populations with a magnetic bead coated with two agents (anti-CD3 and anti-CD28 antibodies) are the same, Creson et al. inherently teach the same process of applying a magnetic force as in the current application. Creson et al. therefore anticipates the step of applying a magnetic force as instantly claimed. The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) and In re Tomlinson, 363 F.2d 928, 150 USPQ 623 (CCPA 1966). See M.P.E.P. § 2112.02.

Although Creson et al. do not particularly disclose regulatory T cells, The "genus" T cells contain very few species comprising regulatory T cells. Given that, the generic T cell disclosure in Creson et al. is sufficiently specific to anticipate applicant's claimed

invention though it is drawn to a species of T cells because one would at once envisage "regulatory T cells" when reading Creson et al.'s "T cell".

M.P.E.P. §2131.02 states "When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

#### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim Patent Examiner Art Unit 1651 Leon B Lankford, Jr Primary Examiner